Docket No.: 03108/0201123-US0

AMENDMENTS TO THE CLAIMS

(Currently amended) β carboline derived guanidine alkaloid, tiruchenduramine of the
 A compound of Formula 1

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and tautomers, stereoisomers, analogs, anhydrides, prodrugs, and pharmaceutically acceptable salts and solvates isolated from an ascidian Synoicum macroglossum and its derivatives thereof.

2. (Currently amended) A compound as claimed in claim 1 having the following formula selected from the following:

wherein n is 2 to 6; Q is NH or O; and R₁ is H or piperazine,

and tautomers, stereoisomers, analogs, anhydrides, prodrugs, and pharmaceutically acceptable salts and solvates thereof.

$$R_1$$
 R_2
 R_3
 R_4
 R_1
 R_1
 R_1
 R_2
 R_3
 R_4
 R_4
 R_4
 R_4
 R_4
 R_4
 R_5
 R_5
 R_5
 R_7
 R_7
 R_7
 R_8
 R_9
 R_9

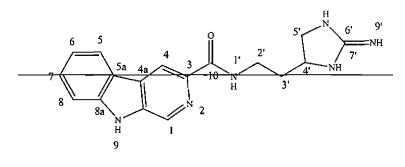
3. (Currently amended) A process for the preparation of <u>a compound according to claim</u>

<u>1</u> β carboline derived guanidine alkaloid tiruchenduramine of Formula 1

which comprises subjecting an ascidian to solvent extraction.

- 4. (Currently amended) A process as <u>claimed</u> in claim 3 wherein said ascidian is Synoicum macroglossum.
- 5. (Previously presented) A process as claimed in claim 3 wherein said extraction comprises extraction in the presence of methanol followed by a dichloromethane:methanol extraction and the extract so obtained is subject to purification.

- 6. (Previously presented) A process as claimed in claim 5 wherein said ascidian comprises freeze dried Synoicum macroglossum.
- 7. (Previously presented) A process as claimed in claim 6 wherein said dichloromethane and methanol are used in a ratio of 1:1.
- 8. (Previously presented) A process as claimed in claim 7 wherein after extraction with dichloromethane and methanol, the extract so obtained is partitioned between water and ethyl acetate.
- 9. (Previously presented) A process as claimed in claim 8 wherein said water extract is lyophilized and the residue is triturated with methanol.
- 10. (Previously presented) A process as claimed in claim 5 wherein said purification comprises a Sephadex LH-20 column chromatography.
- 11. (Currently amended) A pharmaceutical composition comprising as an active ingredient a compound according to claim 1 of Formula 1, and



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a pharmaceutically acceptable carrier, vehicle or excipient.

12. (Currently amended) A pharmaceutical composition comprising as an active ingredient a compound according to as claimed in claim 2 and a pharmaceutically acceptable carrier, vehicle or excipient.

13. (Currently amended) A composition <u>as</u> claimed in claim 11 wherein said composition is used for the treatment of diabetic disorders and wherein said active ingredient is present in an amount of about 78.8 µg.

- 14. (Previously presented) A composition as claimed in claim 13 wherein the unit dosage of said composition is from about 15 mg to about 480 mg.
- 15. (Currently amended) A pharmaceutical composition comprising a first therapeutic agent consisting of a compound according to claim 2 β -carboline derivative guanidine alkaloid, tiruchenduramine selected from the group consisting of compounds 1 through 20 and a second therapeutic agent different from said first therapeutic agent.
- 16. (Previously presented) A composition as claimed in claim 15 wherein said second therapeutic agent is selected from alkylating agents, antimetabolites, vinca alkaloids, antibiotics, cytokines, growth factors and non-steroidal anti-inflammatory drugs.
- 17. (Currently amended) A method of treating diabetic disorders in a mammal in need thereof wherein the method comprises administration of a compound according to claim 2 β -carboline derivative guanidine alkaloid, tiruehenduramine selected from the group consisting of compounds 1 through 20.
- 18. (Currently amended) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a compound according to claim 2 β carboline derivative guanidine alkaloid, tiruchenduramine selected from the group consisting of compounds 1 through 20.
- 19. (Previously presented) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a pharmaceutical composition as claimed in claim 11.
- 20. (Previously presented) A composition as claimed in claim 13 wherein the unit dosage of said composition is from about 24 mg to about 280 mg.

21. (Currently amended) A composition <u>as</u> claimed in claim 12 wherein said composition is used for the treatment of diabetic disorders and wherein said active ingredient is present in an amount of about 78.8 µg.

- 22. (Previously presented) A composition as claimed in claim 21 wherein the unit dosage of said composition is from about 24 mg to about 280 mg.
- 23. (Previously presented) A composition as claimed in claim 21 wherein the unit dosage of said composition is from about 15 mg to about 480 mg.
- 24. (Previously presented) A process as claimed in claim 4 wherein said extraction comprises extraction in the presence of methanol followed by a dichloromethane:methanol extraction and the extract so obtained is subject to purification.
- 25. (Previously presented) A process as claimed in claim 24 wherein said ascidian comprises freeze dried *Synoicum macroglossum*.
- 26. (Previously presented) A process as claimed in claim 25 wherein said dichloromethane and methanol are used in a ratio of 1:1.
- 27. (Previously presented) A process as claimed in claim 26 wherein after extraction with dichloromethane and methanol, the extract so obtained is partitioned between water and ethyl acetate.
- 28. (Previously presented) A process as claimed in claim 27 wherein said water extract is lyophilized and the residue is triturated with methanol.
- 29. (Previously presented) A process as claimed in claim 6 wherein said purification comprises a Sephadex LH-20 column chromatography.
- 30. (Previously presented) A process as claimed in claim 7 wherein said purification comprises a Sephadex LH-20 column chromatography.

- 31. (Previously presented) A process as claimed in claim 8 wherein said purification comprises a Sephadex LH-20 column chromatography.
- 32. (Previously presented) A process as claimed in claim 9 wherein said purification comprises a Sephadex LH-20 column chromatography.
- 33. (Previously presented) A process as claimed in claim 24 wherein said purification comprises a Sephadex LH-20 column chromatography.
- 34. (Previously presented) A process as claimed in claim 25 wherein said purification comprises a Sephadex LH-20 column chromatography.
- 35. (Previously presented) A process as claimed in claim 26 wherein said purification comprises a Sephadex LH-20 column chromatography.
- 36. (Previously presented) A process as claimed in claim 27 wherein said purification comprises a Sephadex LH-20 column chromatography.
- 37. (Previously presented) A process as claimed in claim 28 wherein said purification comprises a Sephadex LH-20 column chromatography.
- 38. (Previously presented) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a pharmaceutical composition as claimed in claim 12.
- 39. (Previously presented) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a pharmaceutical composition as claimed in claim 13.
- 40. (Previously presented) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a pharmaceutical composition as claimed in claim 14.

- 41. (Previously presented) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a pharmaceutical composition as claimed in claim 15.
- 42. (Previously presented) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a pharmaceutical composition as claimed in claim 16.
- 43. (Previously presented) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a pharmaceutical composition as claimed in claim 20.
- 44. (Previously presented) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a pharmaceutical composition as claimed in claim 21.
- 45. (Previously presented) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a pharmaceutical composition as claimed in claim 22.
- 46. (Previously presented) A method of treating a mammal which comprises administering to a mammal in need thereof an effective amount of a pharmaceutical composition as claimed in claim 23.
- 47. (Currently amended) A composition of as claimed in claim 16, wherein the non-steroidal anti-inflammatory is aspirin.